Evaluation and Research (HFD–310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–3150.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that ICN Pharmaceuticals, Inc., 3300 Hyland Ave., Costa Mesa, CA 92626, has filed an application requesting approval for the export of the human drug Benoquin (Monobenzone U.S.P) Cream 20% to Canada. This product is used for the final depigmentation in extensive vitiligo. The application was received and filed in the Center for Drug Evaluation and Research on June 15, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by August 14, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: July 21, 1995.

Betty L. Jones,

Acting Director, Office of Compliance, Center for Drug Evaluaiton and Research.

[FR Doc. 95–19153 Filed 8–2–95; 8:45 am]

BILLING CODE 4160–01–F

Food and Drug Administration

[Docket No. 95D–0162]

Marketing of Condom-like Products: Policy Statement; Notice of Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is making generally available a policy statement issued on February 23, 1994, directly to manufacturers, distributors, and importers of condom products, regarding the marketing of condom-like products. The policy statement is intended to inform manufacturers, distributors, and importers of condoms and condom-like products, including those products labeled or packaged as novelty items, that such products are subject to all of the regulatory requirements for medical devices. This policy statement revises and supersedes the 1989 policy statement regarding the labeling of condoms. FDA is making the policy statement generally available at this time to help ensure that the policy is known and understood by the regulated industry and the public.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the policy statement to the Division of Small Manufacturers Assistance (HFZ–220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6597 (1–800–638–2041 outside MD). Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the policy statement to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the policy statement and received comments are available for pubic examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4765, ext. 157.

SUPPLEMENTARY INFORMATION: On February 13, 1989, FDA issued a statement of policy regarding the marketing of condoms. This policy statement was forwarded via certified mail—return receipt requested—to all manufacturers, importers, and repackagers of condoms for contraception or sexually transmitted disease prevention. Subsequently, FDA discovered that some marketers of functional condom-like products may have misinterpreted the 1989 policy statement, and were marketing functional condoms as novelty items without complying with condom leak testing requirements, current good manufacturing practice (CGMP) regulations, manufacturer registration, product listing, and premarket notification and clearance requirements. Such marketing is in violation of the Federal Food, Drug, and Cosmetic Act (the act) and implementing regulations. Therefore, to clarify that such products may only be legally marketed in compliance with these requirements, FDA issued a new policy statement on February 23, 1994.

Products that are capable of covering the penis with a closely fitting membrane and otherwise have the appearance of a condom are considered to be medical devices, regardless of their packaging or labeling. As such, these products must comply with all the above-referenced requirements. However, when condom-like products cannot be used as condoms, they need not meet the above requirements. For example, a product that resembles a condom but which has the closed end removed, the sides shredded, or the roll permanently sealed so that it is incapable of being unrolled would not be subject to the requirements of the act and the regulations. FDA emphasizes that merely labeling the products as a novelty does not remove it from the scope of the act or in any way exempt it from the requirements applicable to condoms.

Copies of this final policy statement, along with previous policy statements, are available for public examination in the Dockets Management Branch (address above).

Interested persons may, at any time, submit written comments on the final policy statement to the Dockets Management Branch (address above). Such comments will be considered when determining whether to amend the current policy statement. Two copies of any comments are to be

submitted, except that individuals may submit one copy.

Dated: June 23, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95–19089 Filed 8–2–95; 8:45 am]

BILLING CODE 4160–01–F

Food and Drug Administration

Grassroots Regulatory Partnership Meeting; Southwest Region Device Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) (Office of External Affairs, Office of Regulatory Affairs, Office of the Southwest Region, and Center for Devices and Radiological Health) is announcing a free public meeting as a followup to a meeting held in April 1995. The FDA office of the Southwest Region will meet with interested persons in the Southwest Region to address specific issues related to the medical device industry, Southwest Region, and FDA. The agency is holding this meeting to promote the President's initiative for a partnership approach with front-line regulators and the people affected by the work of this agency, and to create local partnerships.

DATES: The public meeting will be held on Friday, August 25, 1995, from 8:30 a.m. to 3:30 p.m.

ADDRESSES: The public meeting will be held at the Sheraton Denver West Hotel, 360 Union Blvd., Lakewood, CO.

FOR FURTHER INFORMATION CONTACT: Virlie Walker, FDA Denver District, Bldg. 20, Entrance W–10, Denver Federal Center, Sixth and Kipling Sts., Denver, CO 80255–0087, 303–236–3018, FAX 303–236–3099.

SUPPLEMENTARY INFORMATION:

Those persons interested in attending this meeting should FAX their comments and registration by Monday, August 21, 1995, including name, firm name, address, and telephone number to 303–236–3099. There is no registration fee for this meeting, but advance registration is required. Space is limited and all interested parties are encouraged to register early.

Dated: July 27, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–19058 Filed 8–2–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0226]

Current Issues in AIDS Clinical Trials; Notice of a Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop on current issues in acquired immune deficiency syndrome (AIDS) clinical trials. The workshop will be followed by a joint meeting of subcommittees of the Antiviral Drugs Advisory Committee and the National Task Force on AIDS Drug Development, announced elsewhere in this issue of the **Federal Register**. The workshop will enable experts in the field of AIDS clinical trials, interested representatives of industry, and interested members of the public to exchange ideas regarding clinical trials of drugs for the treatment of AIDS. While the workshop is not intended to result in consensus among participants or to contribute to the formulation of agency policy, discussions regarding current issues in AIDS clinical trials may provide assistance to pharmaceutical sponsors in designing appropriate study protocols and expediting drug development.

DATES: The public workshop will be held on Wednesday and Thursday, September 6 and 7, 1995, from 8:30 a.m. to 5 p.m. Registration must be received by August 18, 1995.

ADDRESSES: The public workshop will be held at the National Institutes of Health, William H. Natcher Conference Center, 45 Center Dr., 2BC–02, Bethesda, MD. Written comments may be submitted at any time to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. A transcript and summary of the workshop will be available from the Docket Management Branch (address above) and from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Heidi C. Marchand or Kimberley M. Miles, Office of AIDS and Special Health Issues (HF–12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–0104. Persons interested in attending this meeting should FAX their registration to one of the individuals named above at 301–443–9216, including the participant's name; organization name, if any; address; and telephone number. There is no registration fee for any part of this workshop, but advance registration is required. Interested parties are encouraged to register early because space is limited.

SUPPLEMENTARY INFORMATION:

Current Federal regulations allow for the accelerated approval of drugs intended to treat serious and life-threatening diseases, including AIDS and human immunodeficiency virus (HIV)-related diseases, on the basis of clinical trials showing that the drugs have an effect on surrogate endpoints. Following approval, FDA may require that the drug applicant study the drug further to verify the clinical efficacy of the product by performing clinical trials designed to demonstrate therapeutic benefit by clinical endpoints. In AIDS, the clinical endpoints that have been considered meaningful are survival and disease progression as manifested by the development of AIDS-defining opportunistic infections.

One of the major challenges facing developers of HIV therapeutics is the successful design and conduct of the clinical trials intended to provide the data needed to confirm the clinical benefit of drugs that have received accelerated approval. Study design issues include, but are not limited to, choice of patient population, control groups, treatment modifications on study, and analysis of heterogeneous endpoints. Study conduct issues include efficient recruitment of volunteers and retention of study subjects in trials long enough to gather sufficient endpoint data. These studies are being designed and conducted in the context of a rapidly changing world of new information and treatment strategies and increasing reliance on the use of surrogate markers to make treatment decisions.

The goal of this workshop is to discuss critical issues in the conduct of clinical trials in HIV in accelerated approval matters and to suggest strategies to overcome identified obstacles so that new drugs and information on the best use of these new drugs can be made available more quickly.

A transcript and summary of the workshop will be available from the Freedom of Information Office (address above) approximately 10 business days after the workshop at a cost of 10 cents per page.

Interested persons may submit, at any time, to the Dockets Management Branch (address above) comments on the workshop. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the